

**Priority question for written answer P-003603/2023
to the Commission**

Rule 138

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Subject: Mental Health in the Pharmaceutical Package

As members of the MEP Action Group for the Medical Use of Psychedelics, we commend the Commission's efforts to improve access to medicines via the proposed Pharmaceutical Package.

According to OECD¹ half of population will face mental illness. 32 million EU citizens (7.2 %) suffer from chronic depression² with a high suicide risk. WHO Europe reports that 75 % of major depression cases lack adequate treatment³. Up to 50 % of treated patients experience treatment resistance⁴, and nearly one-third of them will attempt suicide⁵. Annually, 130 000 Europeans die by suicide⁶. A recent EC discussion paper 'Scoping study on evidence to tackle high-burden under-researched medical conditions' found that mental disorders top the list⁷, yet last year, none of 89 newly recommended medicines targeted mental health⁸.

1. In view of the above, could the Commission prioritise mental health disorders with targeted research and innovation (R&I) incentives, similar to the case of antimicrobial resistance (AMR), orphan and paediatric therapies?
2. Given that all therapeutic areas have unmet needs, would the Commission agree that prevalence and societal impact should also be a criterion for high unmet medical needs?
3. What actions has the Commission taken to encourage new mental health treatments, and what are the plans in the light of the ongoing review of pharmaceuticals legislation?

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¹ OECD, *A New Benchmark for Mental Health Systems: Tackling the Social and Economic Costs of Mental Ill-Health*, 2021.

² According to Eurostat (2021), 7.2 % of people in the EU suffer from chronic depression.

³ United Nations, Moldova, 2017, 3 out of 4 people suffering from major depression do not receive adequate treatment.

⁴ European Medicines Agency, *Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of depression*, November 2016.

⁵ Bergfeld, I.O., et al., *Treatment-resistant depression and suicidality*, Journal of Affective Disorders, 2018; 7. Dong, M., et al., *Prevalence of suicide attempts in individuals with schizophrenia: a meta-analysis of observational studies*, Epidemiology and Psychiatric Sciences, 2019.

⁶ WHO Europe, *Statement – First meeting of the WHO/Europe Mental Health Coalition – From debate to action*, 2022.

⁷ European Commission, Directorate-General for Research and Innovation, *Scoping study on evidence to tackle high-burden under-researched medical conditions*, 2023.

⁸ European Medicines Agency, *Human medicines: highlights of 2022*, 2023.